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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 09/707,738 | 11/06/2000 | Alessandro Sette | 18623006250 | 8820 |
| 20350 | 7590 | 04/07/2004 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | VANDERVEGT, FRANCOIS P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/707,738 | SETTE ET AL. | |
| | Examiner | Art Unit | |
| | F. Pierre VanderVegt | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003 and 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78 and 79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 08/788,822, which claims the benefit of the filing date of provisional application 60/010,510 and is a continuation-in-part of U.S. Application Serial Number 09/310,462, which is a continuation-in-part of U.S. Application Serial Number 08/485,218, which is a continuation-in-part of U.S. Application Serial Number 08/305,871, which is a continuation-in-part of U.S. Application Serial Number 08/121,101.

Claims 1-77 and 80-83 have been canceled.

Claims 78 and 79 are currently pending and are the subject of examination in the present Office Action.

Priority

1. Applicant is not entitled to priority to 08/305,871 due to lack of support for the pending claims.

Instant base claim 78, first entered as a new claim in the preliminary amendment filed November 6, 2000, is drawn to "[a] peptide of fewer than 30 amino acids, which binds more than one DR allele, the peptide comprising a sequence of the formula $R_1-R_2-R_3-R_4-R_5$, (SEQ ID NO: 26)" wherein " R_1 is a D- or an L-amino acid followed by an alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by a D- or an L-amino acid wherein each of the 2 to 4 amino acids is independently selected from the group consisting of alanine, serine and valine." In the '871 application, the specification at page 4, lines 16-36, discloses " R_1 is a D-amino acid followed by alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine." The specification does not provide other, alternative, definitions for R_1 and R_5 . The '871 application does not support the recitation of R_1 as an "L-amino acid followed by alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine."

The recitation of "a D- or an L-amino acid" for both R_1 and R_5 is not supported by the specification or claims of the '871 patent and the recitation thereof in the instant claims is therefore not entitled to the filing date of the '871 application.

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In addition, support for the recitation cannot be found in U.S. Application Serial Number 08/788,822 or in U.S. Application Serial Number 09/310,462. In fact, neither the '822 nor the '462 application recites the formula $R_1-R_2-R_3-R_4-R_5$ at all.

Accordingly, the instantly claimed invention of claims 78 and 79 is entitled only to the filing date of the instant application and the preliminary amendment filed on even date therewith, which is November 6, 2000.

2. In view of Applicant's amendment and Terminal disclaimers filed December 10, 2003 no outstanding grounds of rejection are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Base claim 78, first entered as a new claim in the preliminary amendment filed November 6, 2000, is drawn to "[a] peptide of fewer than 30 amino acids, which binds more than one DR allele, the peptide comprising a sequence of the formula $R_1-R_2-R_3-R_4-R_5$, (SEQ ID NO: 26)" wherein " R_1 is a D- or an L-amino acid followed by an alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by a D- or an L-amino acid wherein each of the 2 to 4 amino acids is independently selected from the group consisting of alanine, serine and valine." The recitation of "a D- or an L-amino acid" for both R_1 and R_5 is not supported by the specification or claims as originally filed and constitutes new matter.

In the remarks accompanying the preliminary amendment filed November 8, 2000 Applicant positions that "[a]ll support" for the new claims is "provided with reference to the '142 patent" [a.k.a., U.S. Patent No. 5,736,142]. It is acknowledged that the '142 patent was

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issued from the parent application 08/305,871 and that the instant application is a continuation-in-part of the '871 application, filed on September 14, 1994. It is also noted that the instant application (09/707,738) does not recite of the formula $R_1-R_2-R_3-R_4-R_5$ and support for the claims therefore cannot be made by referring to pages in the instant specification. However, it is improper to rely upon the citation of passages in the '142 patent for support of amendments to the instant specification and claims. Support should be pointed out within the specification and/or claims as originally filed of the '871 application, not the patent issued therefrom.

In the '871 application, the specification at page 4, lines 16-36, discloses " R_1 is a D-amino acid followed by alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine." The specification does not provide other, alternative, definitions for R_1 and R_5 . Applicant contends in the remarks accompanying the preliminary amendment filed November 6, 2000 that because "the pan DR peptides of the invention can be synthesized via recombinant DNA techniques, it is clear that pan DR peptides need not include D-amino acids." However, R_1 and R_5 have been defined in the specification in an absolute, not alternative, manner. While pan-DR peptides in general may not require D-amino acids, pan-DR peptides that are instantly described and claimed in terms of the formula $R_1-R_2-R_3-R_4-R_5$ are required to include D-amino acids because R_1 and R_5 are defined by the specification ONLY as D-amino acid residues. The fact that the peptides can be made recombinantly is not relevant because recombinant production does not preclude post-translational modification of the peptide sequence. Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, a limitation for either/each of R_1 or/and R_5 to include "an amino acid" which is not "a D-amino acid" may be obvious over recombinant technology but is not supported by the specification or claims as originally filed. Applicant's assertion in the remarks accompanying the preliminary amendment filed November 8, 2000 that "claim 34 of the '142 patent is directed to pan DR peptides with the exact same amino acid sequences recited in claim 78 of the present application" is

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acknowledged. However, it is noted that claim 34 of the '142 patent was added during prosecution and was not originally presented in the '871 application from which it issued."

Conclusion

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*
Patent Examiner
April 2, 2004

Pat JN12
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

4/5/04